REMARKS

In response the Office Communication mailed November 16, 2004, Applicant is resubmitting the amendment previously mailed on August 24, 2004, to properly amend claim 2, specifically, deleting "thereof," in accordance with 37 C.F.R. 1.21(c)(1)(ii). Applicant submits a complete listing of all claims in order to comply with the revised amendment practice.

Claims 1-3, 7-8, 58 and 59 were previously pending. By this amendment, Applicant has amended claims 2, 3, 58 and 59. New claims 65-71, corresponding to claims 4-6 and 9-10 as originally filed, have been added. The new claims correspond to the invention elected for prosecution. No new matter has been added.

Claims have been canceled without prejudice. Applicant reserves the right to file one or more continuing applications directed to the subject matter present in the cancelled claims.

Defective Declaration

The Examiner indicated that the declaration of the inventors is defective because it does not reference priority application US 60/099,077, filed September 4, 1998. Applicant files herewith an Application Data Sheet that provides the priority information for US 60/099,077 to correct the defect in the declaration. MPEP 601.05.

Objection to the Specification

The Examiner objected to the specification as missing sequence identifiers in the Brief Description of the Drawings for Figs. 6 and 7. The Examiner also objected to the specification as containing hyperlinks.

Applicant has amended the specification to address these matters, and respectfully requests withdrawal of the objection.

Rejections Under 35 U.S.C. 112

1. The Examiner rejected claims 1, 2, 7, 8, 58 and 59 under 35 U.S.C. 112, first paragraph, as lacking an adequate written description. Applicant respectfully traverses the rejection.

The Examiner rejected the claims on the basis that Applicant's specification does not convey to one of ordinary skill in the art that Applicant was in possession of the following:

(1) polypeptides and compositions comprising a functional variant of SEQ ID NO:12, wherein the functional variant is not a substitution variant;

(2) a fragment of SEQ ID NO:5 comprising at least 14 consecutive amino acids of SEQ ID NO:5;

(3) a vaccine comprising an immunogenic fragment of SEQ ID NO:5; and

(4) an isolated immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:12.

Regarding the polypeptides and compositions comprising a functional variant of SEQ ID NO:12, Applicant has amended claim 2 to clarify that the functional variants are functional amino acid substitution variants that retain immunogenicity. This is not indicative of agreement or concession that other types of variants are not adequately described. According to the Examiner, Applicant's specification provides an adequate written description of substitution variants, and therefore Applicant asserts that the claims as amended are adequately described.

Regarding a fragment of SEQ ID NO:5 comprising at least 14 consecutive amino acids of SEQ ID NO:5, Applicant maintains that this aspect of the invention is sufficiently described such that one of ordinary skill in the art would recognized that Applicant invented such polypeptides. Applicant disagrees with the Examiner's statement on page 5 of the Office Action that the term "a fragment of SEQ ID NO:5 comprising at least 14 consecutive amino acids of SEQ ID NO:5" does not specifically define peptides in terms of structural features. Applicant has added to scientific understanding by identifying and disclosing the full amino acid sequence of SEQ ID NO:5. Applicant's specification describes that fragments of this amino acid sequence are part of the invention. Applicant therefore believes that one of ordinary skill in the art would comprehend that Applicant invented the claimed fragments of SEQ ID NO:5.

Regarding a vaccine comprising an immunogenic fragment of SEQ ID NO:5, Applicant has amended claim 58 to strike the word "vaccine". The claimed composition clearly would be understood by one of ordinary skill in the art as having been possessed by Applicant in view of the description in the application.

Regarding an isolated immunogenic polypeptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:12, Applicant identified and described SEQ ID NO:5 in the present application, as noted above. Applicant also identified SEQ ID NO:12 in the application. Applicant described these polypeptides in sufficient detail, including full amino acid sequences and results demonstrating that each is immunogenic. Therefore, one of ordinary skill in the art

certain would understand upon reading Applicant's specification that Applicant did in fact invent these polypeptides and was in possession of same.

Therefore, Applicant's specification provides more than an adequate written description to meet the requirements of the law. Accordingly, in view of the arguments above and claim amendments, Applicant respectfully requests that the rejection for lack of adequate written description be withdrawn.

2. The Examiner rejected claims 1, 2, 7, 8, 58 and 59 under 35 U.S.C. 112, first paragraph, as lacking enablement. Applicant respectfully traverses the rejection.

The Examiner rejected the claims on the basis that Applicant's specification does not enable one of ordinary skill in the art to make and/or use the following:

(1) a vaccine comprising an immunogenic fragment of SEQ ID NO:5;

(2) polypeptides and compositions comprising a functional variant of SEQ ID NO:12, wherein the functional variant is not a substitution variant;

(3) a peptide comprising at least 14 consecutive amino acids of SEQ ID NO:5 that does not consist of SEQ ID NO:12;

(4) a composition comprising SEQ ID NO:12 or a functional variant thereof and a non-alt.M-CSF tumor rejection antigen peptide or precursor; and

(5) an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:12 wherein the polypeptide is not a subsequence of the alt.M-CSF protein.

Regarding a vaccine comprising an immunogenic fragment of SEQ ID NO:5, Applicant has amended claim 58 to strike the word "vaccine". Without conceding the enablement of vaccine compositions as originally claimed and described, the composition as now claimed clearly can be made and used by one of ordinary skill in the art based on the description in the application. Therefore, claim 58 should be enabled as now amended.

Regarding the polypeptides and compositions comprising a functional variant of SEQ ID NO:12, Applicant has amended claim 2 to clarify that the functional variants are functional amino acid substitution variants that retain immunogenicity. This is not indicative of agreement or concession that other types of variants are not enabled by Applicant's specification. In particular, Applicant asserts that only routine experimentation is required to test variants, regardless of the type of variant. Moreover, Applicant's disclosure provides the skilled person

with a starting point to make and test variants. In contrast to the determining a HLA binding peptide using computer predictions, Applicant has provided peptides that have been conclusively demonstrated to bind HLA and to exert subsequent effects. Modifications of this peptide sequence, given the sequence provided by Applicant, can be made as a matter of routine experimentation. As shown in the prior art cited by the Examiner, the person of skill in the art is accustomed to making and testing peptides and variants. Therefore, Applicant asserts that the claims as amended are enabled.

Regarding a peptide comprising at least 14 consecutive amino acids of SEQ ID NO:5 that does not consist of SEQ ID NO:12, Applicant maintains that all fragments of SEQ ID NO:5 are enabled based on Applicant's disclosure. One of ordinary skill in the art knows how to make fragments of proteins – that is entirely routine in the art. Applicant has provided the entire sequence of SEQ ID NO:5 and has taught the skilled person to make fragments that are of at least 14 amino acids in length. Thus no undue experimentation would be required to make and use this aspect of the invention.

Regarding a composition comprising SEQ ID NO:12 or a functional variant thereof and a non-alt.M-CSF tumor rejection antigen peptide or precursor, Applicant has canceled claim 8 that claims this subject matter, without agreeing that the subject matter is not enabled by Applicant's specification, given that many non-alt.M-CSF tumor rejection antigen peptides and precursors are known to the person of ordinary skill in the art (several of which were recited in the application itself, see, e.g., Table I).

Regarding an isolated polypeptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:12 wherein the polypeptide is not a subsequence of the alt.M-CSF protein, Applicant has provided these amino acid sequences, and one of ordinary skill in the art knows how to make and use polypeptides containing these sequences. It would not require undue experimentation for one of ordinary skill in the art to construct a protein having a combination of SEQ ID NO:5 or SEQ ID NO:12 and other polypeptide sequences. Taking one obvious example, it is well known in the art to construct polytopes, which are combinations of peptide epitopes. Applicant provided an extensive description of peptides sequences combinable with the sequences of the invention in polytopes. Other examples of hybrid or fusion proteins are well known in the art, and considering both the sequences of SEQ ID NO:5 and SEQ ID NO:12 are provided, and the techniques needed to construct hybrid or fusion proteins are routine in the

art, it would not have required undue experimentation for one of ordinary skill in the art to practice the invention as claimed.

3. The Examiner rejected claims 3 under 35 U.S.C. 112, second paragraph, as indefinite. Applicant has amended claim 3 to recite "polypeptide" and accordingly Applicant respectfully requests that the rejection of claim 3 be withdrawn.

Rejections Under 35 U.S.C. 102

1. The Examiner rejected claim 58 under 35 U.S.C. 102(b) as being anticipated by Eklund as evidenced by Stites et al. Applicant respectfully traverses the rejection.

According to the Examiner, Eklund teaches a clone that comprises the amino acid sequence AVVGLS, which corresponds to amino acid residues 6-11 of SEQ ID NO:5.

Eklund does not, in fact, teach a fragment of SEQ ID NO:5 as is claimed. Eklund teaches a clone the encodes for a human DNA-binding protein ("rpS1-like" protein) similar to *E. coli* ribosomal protein S1 that includes the same sequence as amino acid residues 6-11 of SEQ ID NO:5. No fragment of the rpS1-like protein is taught by Eklund, and in particular, Eklund does not teach the sequence pulled out by the Examiner as a fragment of the rpS1-like protein. Nor does Eklund teach which piece of the human DNA-binding protein is immunogenic, and in particular Eklund does not teach that the specific amino acid sequence identified by the Examiner is immunogenic.

Therefore, Eklund does not teach the invention claimed in claim 58. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 58 made under 35 U.S.C. § 102(b).

2. The Examiner rejected claim 58 under 35 U.S.C. 102(b) as being anticipated by Watts et al. as evidenced by Stites et al. Applicant respectfully traverses the rejection.

According to the Examiner, Watts teaches a vector that comprises the amino acid sequence GLSPGE, which corresponds to amino acid residues 9-14 of SEQ ID NO:5. The Examiner makes reference to Fig. 2 of Watts, amino acid residues 226-231, as providing the disclosure of the sequence

Watts does not, in fact, teach a fragment of SEQ ID NO:5 as is claimed. Watts teaches a vector the encodes for a *H-2K1*^{k} protein that includes the same sequence as amino acid residues 6-11 of SEQ ID NO:5. No fragment of the *H-2K1*^{k} protein is taught by Watts, and in particular, Watts does not teach the sequence pulled out by the Examiner as a fragment of the *H-2K1*^{k} protein. Nor does Watts teach which piece of the *H-2K1*^{k} protein is immunogenic, and in particular Watts does not teach that this specific fragment is immunogenic.

Therefore, Watts does not teach the invention claimed in claim 58. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 58 made under 35 U.S.C. § 102(b).

CONCLUSION

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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